

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions of claims in the application.

1. (Currently Amended) A method for quantifying ~~[[a]]~~ small particle ~~low-density lipoprotein~~ LDL in a test sample, comprising:

~~(i) removing lipoproteins other than a first step for separating the small particle low density lipoprotein from other low density lipoproteins, and a second step for measuring cholesterol, triglycerides or proteins in the separated small particle low density lipoprotein LDL and HDL from said test sample; and then~~

(ii) quantifying small particle LDL in said test sample from step (i) by measuring the amount of LDL,
wherein step (i) comprises adding a separation agent comprising a polyanion and a divalent cation to said test sample.

2. (Cancelled)

3. (Currently Amended) A method according to claim 1 ~~[[or 2]]~~, wherein said separation agent further comprises a monovalent cation ~~is further used for separating the small particle low density lipoprotein from other low density lipoproteins in said first step.~~

4. (Currently Amended) A method according to claim ~~1 2 or 3~~, wherein the polyanion ~~used in said first step~~ is selected from the group consisting of heparin, phosphotungstic acid and dextran sulfate.

5. (Currently Amended) A method according to ~~any one of claims 2 to 4~~ claim 1, wherein the divalent cation ~~used in said first step~~ is selected from the group consisting of Mn^{2+} , Mg^{2+} and Ca^{2+} .

6. (Currently Amended) A method according to ~~any one of claims 3 to 5~~ claim 3, wherein the monovalent cation ~~used in said first step~~ is selected from the group consisting of Na^+ , K^+ and Li^+ .

7. (Currently Amended) A method according to ~~any one of claims 4 to 6~~ claim 4, wherein, when the polyanion is added to the test sample, the final concentration of the polyanion

is 10-250 U/mL for heparin, 0.02-1.25% for dextran sulfate and 0.02-1.25% for phosphotungstic acid.

8. (Currently Amended) A method according to ~~any one of claims 5 to 7~~ claim 5, wherein, when the divalent cation is added to the test sample, the final concentration of the divalent cation is 2.5-35 mmol/L for Mn^{2+} , 2.5-125 mmol/L for Mg^{2+} and 1-75 mmol/L for Ca^{2+} .

9. (Currently Amended) A method according to ~~any one of claims 6 to 8~~ claim 6, wherein, when the monovalent cation is added to the test sample, the final concentration of the monovalent cation is 0-50 mmol/L.

10. (Currently Amended) A method ~~according to claim 1, for quantifying small particle LDL in a test sample, comprising:~~

(i) removing lipoproteins other than small particle LDL and HDL from said test sample; and then

(ii) quantifying small particle LDL in said test sample from step (i) by measuring the amount of LDL,

~~wherein step (i) comprises adding PEG to said test sample, is used to separate the small particle low density lipoprotein from other low density lipoproteins in said first step.~~

11. (Currently Amended) A method according to claim 10 wherein the final concentration of PEG is 2-5% by weight when PEG is added to the test sample.

12. (Currently Amended) A method according to ~~any one of claims 1 to 11~~ claim 1, wherein measuring the amount of LDL ~~the measurement of cholesterol in said second step~~ is carried out by using a reagent which is used for quantitatively selectively measuring cholesterol in ~~a low density lipoprotein~~ LDL and which does not require fractionation.

13. (Currently Amended) A method according to ~~any one of claims 1 to 11~~ claim 1, wherein measuring the amount of LDL ~~the measurement of triglycerides in said second step~~ is carried out by using a reagent which is used for quantitatively selectively measuring triglycerides in ~~a low density lipoprotein~~ LDL and which does not require fractionation.

14. (Currently Amended) A method according to ~~any one of claims 1 to 11~~ claim 1, wherein ~~measuring the amount of LDL the measurement of protein in said second step~~ is carried out by using an anti-human apoprotein B antibody.

15. (Currently Amended) A method for separating ~~[[a]] small particle low density lipoprotein LDL~~ from a test sample that contains LDLs, comprising ~~a step in which the low density lipoprotein precipitating LDLs~~ other than small particle low density lipoproteins is ~~precipitated LDL~~ by adding a separation agent comprising a polyanion and a divalent cation to the test sample.

16. (Currently Amended) A method according to claim 15, wherein said separation agent further comprises a monovalent cation ~~comprising a step in which the low density lipoprotein other than small particle low density lipoproteins is precipitated by also adding a monovalent cation to the test sample.~~

17. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to claim 15 ~~[[or 16]]~~, wherein the polyanion is selected from the group consisting of heparin, phosphotungstic acid and dextran sulfate.

18. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to ~~any one of claims 15 to 17~~ claim 15, wherein the divalent cation is selected from the group consisting of Mn^{2+} , Mg^{2+} and Ca^{2+} .

19. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to ~~any one of claims 15 to 18~~ claim 15, wherein the monovalent cation is selected from the group consisting of Na^{+} , K^{+} and Li^{+} .

20. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to ~~any one of claims 17 to 19~~ claim 17, wherein, when the polyanion is added to the test sample, the final concentration of the polyanion is 10-250 U/mL for heparin, 0.02-1.25% for dextran sulfate and 0.02-1.25% for phosphotungstic acid.

21. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to ~~any one of claims 18 to 20~~ claim 18, wherein, when the divalent cation

is added to the test sample, the final concentration of the divalent cation is 2.5-35 mmol/L for Mn^{2+} , 2.5-125 mmol/L for Mg^{2+} and 1-75 mmol/L for Ca^{2+} .

22. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to ~~any one of claims 19 to 21~~ claim 16, wherein, when the monovalent cation is added to the test sample, the final concentration of the monovalent cation is 0-50 mmol/L.

23. (Currently Amended) A method for separating a small particle low density lipoprotein from a test sample that contains LDLs, comprising ~~a step in which PEG is added to the test sample to precipitate the low density lipoprotein~~ precipitating LDLs other than small particle low density lipoproteins LDL by adding PEG to the test sample.

24. (Currently Amended) A method ~~for separating a small particle low density lipoprotein~~ according to claim 23, wherein the final concentration of PEG is 2-5% by weight when PEG is added to the test sample.

25. (Currently Amended) A kit for measuring ~~[[a]]~~ small particle ~~low density lipoprotein~~ LDL in a test sample, comprising:

(i) a surface active agent, which is selected from the group consisting of polyoxyethylene lauryl ether, polyoxyethylene cetyl ether, polyoxyethylene octylphenyl ether and polyoxyethylene nonylphenyl ether;

(ii) a separation agent that ~~includes~~ comprises a polyanion and a divalent cation, wherein the polyanion is selected from the group consisting of heparin, phosphotungstic acid and dextran sulfate; and

(iii) a reagent for measuring ~~the low density lipoprotein~~ LDL via measuring, wherein the ~~kit measures~~ cholesterol, triglycerides or proteins in the ~~small particle low density lipoprotein~~ LDL.

26. (Currently Amended) A kit ~~for measuring a small particle low density lipoprotein~~ according to claim 25, wherein the separation agent further ~~includes~~ comprises a monovalent cation.

27. (Currently Amended) A kit for measuring ~~[[a]] small particle low-density lipoprotein~~ LDL in a test sample, comprising:

(i) a surface active agent, which is selected from the group consisting of polyoxyethylene lauryl ether, polyoxyethylene cetyl ether, polyoxyethylene octylphenyl ether and polyoxyethylene nonylphenyl ether;

(ii) a separation agent that ~~includes~~ comprises PEG; and

(iii) a reagent for measuring ~~the low-density lipoprotein~~ LDL via measuring, wherein the kit measures cholesterol, triglycerides or proteins in the ~~small particle low-density lipoprotein~~ LDL.

28. (Cancelled)

29. (Currently Amended) A kit according to claim 26 ~~or 28~~, wherein the divalent cation is selected from the group consisting of Mn^{2+} , Mg^{2+} and Ca^{2+} and the monovalent cation is selected from the group consisting of Na^{+} , K^{+} and Li^{+} .

30. (New) A kit according to claim 25, wherein the separation agent comprises 60 U/mL of sodium heparin and 40 mmol/L of $MnCl_2$, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

31. (New) A kit according to claim 25, wherein the separation agent comprises 300 U/mL of sodium heparin and 150 mmol/L of $MgCl_2$, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

32. (New) A kit according to claim 25, wherein the separation agent comprises 1.5% dextran sulfate with an average molecular weight of 5000 and 40 mmol/L of $MgCl_2$, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

33. (New) A kit according to claim 25, wherein the separation agent comprises 0.3% sodium phosphotungstic acid and 7.5 mmol/L of $CaCl_2$, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

34. (New) A kit according to claim 25, wherein the separation agent comprises 40 U/mL sodium heparin and 30 mmol/L of $MnCl_2$, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

35. (New) A kit according to claim 25, wherein the separation agent comprises 500 U/mL sodium heparin, 140 mmol/mL MgCl_2 and 34 mmol/L of KCl, and wherein the separation agent is added to the test sample at a volume ratio of 1:1.

36. (New) A kit according to claim 25, wherein the separation agent comprises 150 U/mL sodium heparin, 90 mmol/mL MgCl_2 , and wherein the separation agent is added to the test sample at a volume ratio of 1:1.